AUG 2 1 2002

K022453

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

July 25, 2002

Submitter

Welch Allyn Protocol, Inc.
8500 S.W. Creekside Place
Beaverton, OR 97008-7107
USA

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Contact: Mr. Donald M. Abbey, Vice President, Quality Systems

Device Name

Trade Name:
Common Name: Cardiac Arrhythmia Monitor
Classification Name: Arrhythmia Detector and Alarm (Reference, 21 CFR 870.1025, April 1, 2001).

Device Classification

Regulatory Class III

Predicate Device

Substantial equivalence is based on the current Acuity system, which consists of the Acuity® Central Monitoring Station, Acuity software, FlexNet™ communications network, Welch Allyn vital signs monitors, and the Mortara H-Scribe Holter system. The Acuity® Central Monitoring Station and Acuity software were cleared for market by the FDA under 510(k) submissions K913193, K935846 and K972121. The FlexNet™ communications network was cleared for market as part of K002725. The FlexNet™ communications network has not changed from the original submission. The software in the Acuity® Central Monitoring Station has changed. The Arrhythmia monitoring and ST analysis software module has changed. Welch Allyn Protocol, Inc. has purchased the rights to use an arrhythmia monitoring and ST analysis software module developed by Mortara Instruments, Inc. It contains the same software used in the Mortara H-Scribe Holter System that was cleared for market under K004017. This software replaces the Arrhythmia monitoring and ST analysis software modules currently in the Acuity® Central Monitoring Station.

Device Description

The Acuity system comprises four components: the Acuity Central Monitoring Station, Acuity software, the FlexNet™ communications network, and Welch Allyn vital signs monitors. The Acuity Central Monitoring Station is the heart of the system, using hardware provided by Sun Microsystems, Inc. The Acuity Central Monitoring Station communicates with network devices on the FlexNet network using hardwired Ethernet connections (IEEE 802.3-compliant) or wireless Ethernet connections (IEEE 802.11-compliant).

The Acuity software operating system is Solaris™, the Unix®-based operating system from Sun Microsystems. Welch Allyn Protocol's application software provides the routines and services required to accomplish the tasks associated with central patient monitoring. These tasks include the user interface, communication with patient monitors, management of alarms and settings, and recording and review of patient data.

The Arrhythmia Analysis and ST Analysis options are being replaced with Mortara Instrument's arrhythmia algorithm software module. Mortara Instrument's arrhythmia software will now provide the data analysis for both the Arrhythmia Analysis and the ST Analysis options.

The Acuity application software receives the output from the Mortara software module and records the results in the same manner as the previous version of Acuity software. There are only a few minor changes to the user interface as described in the Acuity Directions For Use.

The Acuity hardware and software operating system are not changed.

Indications for Use
The Acuity® system is intended to be used by skilled clinicians for the central monitoring of neonatal, pediatric, and adult patients in health care facilities. The Acuity system consists of the Acuity® Central Monitoring Station, Acuity software, FlexNet™ communications network and Welch Allyn vital signs monitors. The vital signs monitors can operate standalone (according to their individual Intended Use Statement) or be networked to the Acuity central monitoring station through the Acuity FlexNet communication network.

In addition to the central monitoring of patient data, waveforms, alarms and alerts, the Acuity software can include optional modules to provide extended recording of patient data, arrhythmia monitoring and ST analysis.

- Full disclosure stores patient data for up to 96 hours.
- Arrhythmia monitoring module provides real-time monitoring and alarms for specific changes in cardiac rhythms. The clinician is responsible for determining the clinical significance of each detected arrhythmia event or alarm. The arrhythmia module is not intended for use with neonatal patients.
- ST analysis module provides real-time monitoring and alarms for ST segment deviations, from a reference beat, for patients with suspected heart disease and anomalies. The clinician is responsible for determining the clinical significance of each detected ST segment deviation or alarm. The ST analysis module is not intended for use with neonatal patients.

The most likely locations for patients monitored by an Acuity system are step-down units, telemetry departments, general med/surg floors and emergency departments. The Acuity system is available for sale only upon the order of a physician or licensed health care professional.

Technological Comparison to the Predicate Device
The Acuity system is comprised of 4 components, the Acuity Central Monitoring Station, Acuity Software, FlexNet communication network, and Welch Allyn vital signs monitors. The Acuity Central Monitoring Station is the heart of the system. It provides the user interface, control, data processing and data storage for the system. The central monitoring station is a UNIX workstation that only supports the Sun Microsystems architecture. Except for the Acuity software, the Acuity system is the same as system(s) [illegible] under the above referenced 510(k) submissions.

The arrhythmia module in the Acuity software has changed. It has been replaced by a proprietary software package developed and marketed by Mortara Instruments, Inc. The Mortara software module contains the same arrhythmia algorithms used in their H-Scribe Holter system. The Mortara software module is a self-contained software package that receives and process ECG signals from the systems, and provides outputs in the form of measurements and event markers. The Acuity Software processes the outputs to create displays, alarms, messages, trends and other system services such as printing.

Summary of Performance Testing

Module tests demonstrated that there was improved performance with the Mortara software module, in that Mortara software module out performed the current arrhythmia module in the Acuity system. It also proved that integration of the Mortara module would have a minimum impact on the existing Acuity software, such as displays, alarms, trending control and communications.

Test data from the two units noted above were compared and found to be identical with the exception of one test case. The Mortara software module labeled one of the 1600 beats incorrectly.

A standalone (non-networked) Acuity system with a single patient monitor connected was also tested with the same playback files. The data from this system was then compared with the data from that of a fully configured (networked) system. Analysis showed that 100% of the QRS complexes were detected and the arrhythmia events were correctly identified (labeled) with less than 3% event false positives. Less than 1% of the ventricular beats were mislabeled. In one test case, which included 1600 beats, three ventricular beats were mislabeled, resulting in one less false positive event identification. This was observed for one of the monitors from the fully loaded system.

A risk analysis, identifying potential hazards and documenting mitigation of the hazards, has been developed and verified/validated as part of Welch Allyn Protocol's product development procedures. Welch Allyn Protocol's Quality System conforms to 21CFR820 and is certified by TUV Product Service to ISO 9001 and EN46001.

Conclusions

As stated above, Welch Allyn Protocol's conclusion is that the Acuity system with Cardiac Arrhythmia and ECG ST Analysis options are safe, effective, comply with the appropriate medical device standards, and offer improved performance compared to Acuity system with Cardiac Arrhythmia and ECG ST Analysis options currently on the market.

This *510(k) Summary of Safety and Effectiveness* may be copied and submitted to interested parties as required by 21CFR807.92.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 21 2002

Welch Allyn Protocol, Inc.
c/o Mr. Donald M. Abbey
Vice President, Quality Systems
8500 S.W. Creekside Place
Beaverton, OR 97008-7107

Re: K022453
Trade Name: Acuity® Central Monitoring Station
Regulation Name: Arrhythmia Detector and Alarm
Regulation Number: 21 CFR 870.1025
Regulatory Class: Class III (three)
Product Code: DSI
Dated: July 25, 2002
Received: July 26, 2002

Dear Mr. Abbey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

Applicant:
Welch Allyn Protocol. Inc.
8500 SW Creekside Place
Beaverton, OR 97008-7107
USA

Telephone: (503) 526-8500
Fax: (503) 526-4200

510(k) Number: _____

Device Name: Acuity® Central Monitoring Station

Indications for Use:
The Acuity® system is intended to be used by skilled clinicians for the central monitoring of neonatal, pediatric, and adult patients in health care facilities. The Acuity system consists of the Acuity® Central Monitoring Station, Acuity software, FlexNet™ communications network and Welch Allyn vital signs monitors. The vital signs monitors can operate standalone (according to their individual Intended Use Statement) or be networked to the Acuity central monitoring station through the Acuity FlexNet communication network.

In addition to the central monitoring of patient data, waveforms, alarms and alerts, the Acuity software can include optional modules to provide extended recording of patient data (Full Disclosure), arrhythmia monitoring and ST analysis.

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The most likely locations for patients monitored by an Acuity system are step-down units, telemetry departments, general med/surg floors and emergency departments. The Acuity system is available for sale only upon the order of a physician or licensed health care professional.

(Please do not write below this line – continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The Counter _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Cardiovascular
and Respiratory Devices

510(k) Number K022453